

REMARKS

As a preliminary matter, claims 45 and 99 stand rejected under 35 U.S.C. § 112, 2nd paragraph, as being indefinite. In view of the cancellation of claims 99-114, this rejection of claim 99 is considered moot. However, the Examiner will note that claim 45 has been amended to overcome this rejection. More specifically, claim 45 has been amended to provide proper antecedent basis from claim 44. Favorable reconsideration of claim 45 is therefore respectfully requested.

Also as a preliminary matter, the Examiner has indicated that claims 28, 41-43, 77, and 86-94 are objected to and would be allowable if rewritten in independent form. Accordingly, claims 28, 41, 77, and 86 have been so amended. Additionally, claim 44 has been amended to be dependent from claim 41 and claim 89 has been amended to be dependent from claim 86. Claims 42 and 43 depend from claim 41, and claims 45 and 46 depend from claim 44. Accordingly, claims 28, 41-46, 77, and 86-94 are all considered to be in condition for allowance. Such favorable action is respectfully requested.

With respect to the rejections based upon the cited prior art, claims 1-7, 14, 47, 48, 50-54, 63-67, and 76 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hart, U.S. Patent No. 5,626,614. Claims 1, 8, 11, 12, 16, 17, 21, 32-38, 47, 55, 58, 59, 60, 68, 78-84, 89, and 90 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Frazier, et al., U.S. Patent No. 6,419,669. The rejection of claims 99-102 and 106-109 under 35 U.S.C. § 102(e) as being anticipated by DeVries, et al., U.S. Patent No. 7,083,630 is rendered moot by virtue of the cancellation of claims 99-114.

Claims 16-20, 27, 61, and 62 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart in view of Sgro, et al., U.S. published application 2005/0004575. Claims 15, 24, 49, and 71 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart or the combination of Hart and Sgro and further in view of Makower, et al., U.S. Patent No. 6,491,707. Claims 25, 30, 31, and 73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart, the combination of Hart and Makower, and the combination of Hart, Sgro, and Makower, and further as a matter of

design choice. Claims 26 and 75 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Hart and Sgro as applied to claims 1, 16, 47, and 61 above, and further in view of Suzuki et al., U.S. published application 2003/0216613. Claims 9, 22, 56, 10, 23, 57, 69, and 70 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Frazier, et al. in view of Hart and further as a matter of design choice. Claims 29 and 98 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart as a matter of design choice. Claims 72 and 74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Hart and Makower, and further as a matter of design choice. Claims 95-97 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart in view of Makower, and further as a matter of design choice. Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hart in view of Cragg, U.S. Patent No. 6,315,789. Claims 39, 40, and 85 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Frazier, et al. as a matter of design choice. The 35 U.S.C. § 103(a) rejections of claims 103, 104, 105, and 110-114 is rendered moot by the cancellation of claims 99-114.

Lastly, claims 1-5, 15-20, 24-26, 33, 34-38, 44-54, 61-62, 67, 71, 73, 80-84, 89, and 90 stand provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-36 of copending Application No. 10/949,737. This last rejection is respectfully traversed in as much as there is no claim pending in the present application that is identical to or claims the same invention as any claim in copending Application No. 10/949,737. As may be clearly noted, each of the independent claims of copending Application No. 10/949,737 defines a fastener wherein one of the first and second members includes a slot communicating with a through channel of the member, such slot being dimensioned to receive the tissue piercing deployment wire. The present application does not have a claim defining such structure. It is thus respectfully requested that the 35 U.S.C. § 101 rejection be withdrawn.

With respect to the aforementioned rejections based upon the prior art, each of these rejections and the cited prior art have been carefully reviewed and considered. It is respectfully submitted that for the reasons stated hereinafter, the claims remaining at issue, namely claims 1-27, 29-40, 47-76, 78-85, and 95-98 are in condition for

allowance over the applied prior art. Accordingly, favorable reconsideration of these claims is respectfully requested.

With respect to the 35 U.S.C. § 102(b) rejection of claims 1-7, 14, 47, 48, 50-54, 63-67, and 76 based upon Hart, U.S. Patent No. 5,626,614, this rejection is respectfully traversed. It is respectfully submitted that Hart fails to show, describe, or even suggest the invention as defined in those claims. To demonstrate such allowability over Hart, the foregoing remarks will be specifically directed to independent claims 1 and 47. The allowability of dependent claims 2-7, 14, 48, 50-54, 63-67, and 76 will be made clear in view of the remarks submitted hereinafter with respect to independent claims 1 and 47.

The fastener defined in claims 1 and 47 is substantially H-shaped. The fastener includes a first member, a second member, and a connecting member fixed to each of the first and second members intermediate their ends. The connecting member extends between the first and second members and separates the first and second members. One of the first and second members has a through channel along a longitudinal axis arranged to be slidably received on a tissue piercing deployment wire. The member arranged to be received on the tissue piercing deployment wire may be pushed along the tissue piercing deployment wire and through the layers of tissue to be fastened. The other one of the first and second members trails behind and self deploys as the leading member is pushed off of the self piercing deployment wire. As a result, the fastener is self deploying upon being removed from the tissue piercing deployment wire.

In view of the above, claim 1 calls for a fastener for use in a mammalian body comprising a first member, a second member, the first and second members having first and second ends, and a connecting member fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members. Claim 1 further calls for the first and second members being separated by the connecting member and one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidably received on a tissue piercing deployment wire. Claim 47 defines a fastener assembly which includes the fastener recited in claim 1 and further calling for a deployment wire

that slidingly receives the through channel of the one of the first and second members and pierces into the tissue and a pusher that pushes the one of the first and second members into the tissue while on the deployment wire.

It is respectfully submitted that Hart fails to show, describe, or even suggest a fastener defined in claim 1 or the assembly defined in claim 47. More specifically, Hart fails to show, describe, or even suggest a fastener having a connecting member fixed to each one of the first and second members intermediate the first and second ends and extending between the first and second members and the first and second members being separated by the connecting member as defined in claims 1 and 47.

With respect to the connecting member being fixed to each of the first and second members, Hart expressly describes the bolster 16 to be slidable along the suture 14. Hence, the bolster 16 is not fixed to a connecting member as defined in claim 1. Even after a suture knot is made in the suture 14, the bolster 16 is still not fixed to the suture 14. As a result, Hart fails to show, describe, or even suggest "a connecting member fixed to each of the first and second members" as clearly defined in claims 1 and 47.

Secondly, with respect to the first and second members being separated by the connecting member as defined in claims 1 and 47, once again, the connecting member of the Hart reference is a suture. As is well known in the art, the design intent of a suture is to have a very high tensile stiffness relative to bending and torsional stiffness, allowing it to carry very high tensile loads when suturing tissue without requiring high bending or torsional loads to be overcome when forming loops or knots during the suturing process. Thus, in the free state, the member 12 and bolster 16 of Hart will not maintain their specific orientations relative to each other because the suture lacks the bending and torsional stiffness to maintain such relative positions of the member 12 and bolster 16. Hence, a reasonable interpretation of the Hart reference could not attribute the function of the suture to include separating the member 12 and bolster 16 in direct contrast to what is defined in claims 1 and 47 and more specifically "the first and second members being separated by the connecting member".

As may be clearly seen from the foregoing, Hart fails to anticipate claims 1-7, 14, 47, 48, 50-54, 63-67, and 76 as advanced in the Office Action. Hart fails to show, describe, or even suggest the first and second members being separated by the connecting member, or the connecting member being fixed to each of the first and second members. As a result, the structure and function of the fastener defined in claims 1 and 47 is entirely different than that of the fastener described in Hart. More specifically, the fastener of the present invention by virtue of its structure is self deployable whereas the Hart fastener is not. Once the leading member of the Hart fastener is placed in position, the trailing member must then be secured to the suture. The Hart fastener is hardly self deployable in direct contrast to the fastener of the present invention by virtue of the connecting member being fixed to each of the first and second members intermediate the first and second ends and the first and second members being separated by the connecting member as defined in claims 1 and 47. Hence, claims 1-7, 14, 47, 48, 50-54, 63-67, and 76 are clearly allowable over the 35 U.S.C. § 102(b) rejection based upon Hart. Favorable reconsideration and withdrawal of the rejection is respectfully requested.

The 35 U.S.C. § 102(b) rejection of claims 1, 8, 11, 12, 16, 17, 21, 32-38, 47, 55, 58, 59, 60, 68, 78-84, 89, and 90 based upon Frazier, et al., U.S. Patent No. 6,419,669 is also respectfully traversed. It is respectfully submitted that since independent claims 1 and 47 define a fastener nowhere shown, described, or even suggested in Frazier, et al., each of the foregoing claims subject to the 35 U.S.C. § 102(b) rejection under Frazier, et al. is clearly allowable. It is respectfully submitted that a reasonable interpretation of Frazier, et al. would fail to support the 35 U.S.C. § 102(b) rejection advanced in the Office Action.

The Office Action makes specific reference to FIG. 18 of Frazier, et al. More specifically, FIG. 18 of Frazier, et al. relates to a structure termed an anchor. As described beginning at column 15, line 4, the anchor 90 comprises a proximal end 130, a distal end 132, and a central lumen 134 extending therebetween. The anchor has a first proximal projection 136 and a second proximal projection 138 on a tubular body 92. The projections 136, 138 are designed to enlarge radially outwardly in response to axial

compression of the anchor 90. The anchor 90 further includes a first distal projection 140 and a second distal projection 142 on the tubular body 92 which also expand radially outwardly in response to axial compression of the anchor.

The central lumen 134 accommodates an introducer 96 having a sharpened distal end 100. After the anchor 90 is placed, a suture 150 is pulled to impart an axial compression force on the anchor 90 causing the anchor to axially collapse and the projections 136, 138 and 140, 142 to expand radially outwardly. As the anchor collapses axially, the projections confine tissue between tissue contact surfaces 144 and 146.

It is respectfully submitted that the anchor of Frazier, et al. is entirely different in structure and function from the fastener defined in claims 1 and 47. First, as stated previously, claims 1 and 47 define a fastener having a first member, a second member, the first and second members having first and second ends, and a connecting member fixed to each of the first and second members intermediate the first and second ends as extending between the first and second members. It is respectfully submitted that this structure is not shown or described in FIG. 18 of Frazier, et al. In the Office Action, the proximal end 130 is taken to be the first member, and distal end 132 is taken to be the second member, the second distal projection 142 is taken as the first end (presumably of both the recited first and second members) and the tissue contact surface 146 is taken as the second end (also presumably of both the first and second members). It is respectfully submitted that Frazier, et al. cannot be reasonably applied to the recited claim language. It is not seen how the proximal end 130 may be taken to correspond to the recited first member, how the distal end 132 can be taken as the recited second member, and how the tubular body 92 may be considered to be coupled between first and second ends of the proximal end 130 and distal end 132.

Still further, claims 1 and 47 further define the fastener as one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidingly received on a tissue piercing deployment wire. It is respectfully submitted that Frazier, et al. fails to show, describe, or even suggest this structure. This recited limitation clearly calls for a lengthwise axis along one of the first and

second members and a through channel along the lengthwise axis arranged to be slidingly received on a tissue piercing deployment wire. It is respectfully submitted that Frazier, et al. fails to show, describe, or even suggest such a lengthwise axis and through channel along such a lengthwise axis. In the Office Action, the central lumen 134 is taken as the recited through channel. However, the central lumen 134 does not extend along a longitudinal axis of a first and second member as claimed. Rather, the central lumen transversely crosses the lengthwise dimension of the projections. Hence, neither one of the projections has a through channel extending along a longitudinal axis of the projection. After the anchor 90 of FIG. 18 reaches its final configuration as shown in FIG. 20, it can be clearly seen that the central lumen 134 does not extend along a longitudinal axis of a first and second member as defined in claims 1 and 47. Rather, the central lumen 134 still extends transverse to any such longitudinal axis of the projections.

Because of the structural differences noted above between the anchor 90 of FIG. 18 of Frazier, et al. and the fastener defined in claims 1 and 47, the anchor 90 cannot function in the same manner as the fastener defined in claims 1 and 47. Not one of the projections 136, 138, 140, and 142 is capable of having a through channel along a longitudinal axis as defined in claims 1 and 47. The tubular body 92 is not between first and second ends of projections 136, 138, 140, and 142. The manner of delivering the anchor 90 is entirely different than the manner of delivering the fastener defined in claims 1 and 47. Lastly, the manner of deploying the anchor 90 of FIG. 18 in Frazier, et al. is entirely different than the manner of deploying the fastener defined in claims 1 and 47. The fastener defined in claims 1 and 47 is clearly self deployable whereas the anchor 90 is not. More specifically, once the anchor 90 reaches its final location, the suture 150 must be pulled to compress the anchor to cause the projections 136, 138, 140, and 142 to expand radially outwardly to confine tissue between the tissue contacting surfaces 146 and 144.

It is respectfully submitted that the foregoing demonstrates the clear differences between the anchor 90 of Frazier, et al. and the fastener defined in claims 1 and 47. It is respectfully submitted that claims 1 and 47 are not anticipated by Frazier, et al.

Accordingly, it is respectfully requested that the 35 U.S.C. § 102(b) rejection of claims 1 and 47 based upon Frazier, et al. be withdrawn. Similarly, and for the same reasons, claims 8, 11, 12, 16, 17, 21, 32-38, 55, 58, 59, 60, 68, 78-84, 89, and 90 are considered to be clearly allowable over the 35 U.S.C. § 102(b) rejection as well. Favorable reconsideration of these claims is also respectfully requested.

In view of the clear deficiencies of Hart and Frazier, et al. with respect to independent claims 1 and 47 as demonstrated above, the rejection of all remaining dependent claims are respectfully traversed. The prior art references cited in combination with Hart or Frazier, et al. in support of the obviousness rejections of these claims fail to provide the necessary description lacking in Hart and Frazier, et al. to render each of these claims obvious in combination with Hart or Frazier, et al. Accordingly, favorable reconsideration of claims 9, 10, 13, 15-20, 22-27, 29-31, 39, 40, 49, 56, 57, 61, 62, 69-75, and 95-98 is respectfully requested.

CONCLUSION

With this Response, the application is considered in condition for allowance. Such favorable reconsideration is respectfully solicited.

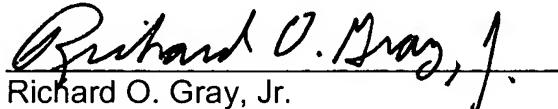
In the event additional fees are due as a result of this response, payment for those fees has been enclosed in the form of a check. Should further payment be required to cover such fees you are hereby authorized to charge such payment to Deposit Account No. 07-1897.

If the Examiner believes that a phone interview would be helpful, she is respectfully requested to contact the Applicant's attorney, Richard O. Gray, Jr., at (425) 455-5575.

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Respectfully submitted,

GRAYBEAL JACKSON HALEY LLP


Richard O. Gray, Jr.
Attorney for Applicants
Registration No. 26,550
155-108th Avenue N.E., Ste 350
Bellevue, WA 98004-5973
(425) 455-5575